Iovate Health Sciences U.S.A. Inc.

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800) Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

NOTIFICATION OF STATEMENT OF NUTRITIONAL SUPPORT

JUL 1 3 2004

Dear Sir or Madam:

In accordance with Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, and pursuant to 21 C.F.R. § 101.93, we hereby provide the following notice with regard to the marketing of the Dietary Supplement described below:

Distributor: Iovate Health Sciences U.S.A. Inc., 3880 Jeffrey Blvd., Hamburg, NY 14219

Name of Supplement: **NITRO-TECH NIGHTTIME**TM (various flavors)

Statement of Nutritional Support:

- Supports Muscle Growth At Night
- As a part of your diet and training plan, NITRO-TECH Nighttime is designed specifically to help you build muscle as you sleep.
- The result as part of your diet and training plan, taking NITRO-TECH Nighttime before bed helps you build muscle while you sleep.

To the best of my knowledge, the information contained in this notice is complete and accurate, and Iovate Health Sciences U.S.A. Inc. has substantiation that the statements are truthful and not misleading.

Sincerely

Shan Chaudhuri

Regulatory Affairs Manager

Date: July 8, 2004

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